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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/646,486 | 08/22/2003 | Eric Ryba | 11350.23 | 9316 |
| 23862 | 7590 | 12/16/2005 | EXAMINER | |
| NYDEGGER & ASSOCIATES | | | ROLLINS, ROSILAND STACIE | |
| 348 OLIVE STREET | | | ART UNIT | |
| SAN DIEGO, CA 92103 | | | PAPER NUMBER | |

3739

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,486

Applicant(s)

RYBA, ERIC

Examiner

Rosiland S. Rollins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 September 1950.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lalonde et al. (US 6283959), Benson (US 4082096), Dobak, III (US 6482226) and further in view of Kudravalli et al. (US 6471694). Lalonde et al. disclose a device for cryoablating exposed tissue comprising a tube-shaped shaft (10), a flexible enclosure (203) and a means for cooling (201) the enclosure to cryoablate tissue. Lalonde et al. '959 teach all of the limitations of the claims except a shapeable element attached to the distal end of the shaft and extending therefrom into the cryochamber, a high pressure tube with a capillary tube connected in fluid communication with the distal end of the high pressure tube and a preconditioned cryo-fluid.

Benson discloses a cryoablation device that includes a shapeable element that helps to maintain the desired configuration of the tip and provide a means of pressing the probe tip into engagement with tissues. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a shapeable element on the Lalonde et al. device as taught by Benson to help maintain the desired configuration of the tip. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the rod to the

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distal end of the shaft, since it has been held that rearranging parts of an invention only involves routine skill in the art.

Dobak, III disclose a similar apparatus and teach that it is old and well known to include a high pressure tube with a capillary tube connected in fluid communication with the distal end of the high pressure tube since it allows cooling to be focused at the flexible enclosure and eliminates cooling along the catheter body (col. 4 lines 27-39; col. 6 lines 9+). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a supply tube with a coaxial capillary tube extending distally therefrom on the Lalonde et al. device, particularly in view of the teaching of Dobak, III.

Kudaravalli et al. disclose a control system for cryosurgery and teach that it is old and well known in the art to precondition the cryofluid to achieve and maintain an optimal flow rate of the cryofluid. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to precondition the cryofluid of Lalonde et al. as disclosed by Kudaravalli et al. to establish and maintain an optimal flow rate of the cryofluid. It would have also been obvious to precondition the cryofluid at the claimed pressure and temperature since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Response to Arguments

Applicant's arguments filed 9/20/05 have been fully considered but they are not persuasive.

Regarding the argument that Lalonde et al. do not teach or suggest any structure that shapes the balloon to conform it to exposed tissue, Examiner would like to point out that Lalonde et al. was not relied upon for teaching this limitation.

Applicant argues that the Benson rod is not attached to the distal end of the shaft and the porous mass of Benson cannot be said to form a rod. It has been held that rearranging parts of an invention only involves routine skill in the art, therefore attaching the rod to the distal end of the shaft only involves routine skill. The porous mass of Benson was not relied upon for teaching the rod. The rod 17 of Benson is shapeable as clearly illustrated in the drawings.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosiland S. Rollins whose telephone number is (571) 272-4772. The examiner can normally be reached on Mon.-Fri. 9:00 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rosiland S Rollins
Primary Examiner
Art Unit 3739

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